

REQUEST FOR ACCESS TO AN ABANDONED APPLICATION UNDER 37 CFR 1.14

Bring completed form to:
File Information Unit
Crystal Plaza Three, Room 1D01
2021 South Clark Place
Arlington, VA
Telephone: (703) 308-2733

RECEIVED

SEP 01 2006

File Information Unit

In re Application of

Application Number

08/355460

Filed

12-13-94

Paper No.

#30

I hereby request access under 37 CFR 1.14(a)(1)(iv) to the application file record of the above-identified ABANDONED application, which is identified in, or to which a benefit is claimed, in the following document (as shown in the attachment):

United States Patent Application Publication No. _____, page, _____ line _____.

United States Patent Number 6015567, column _____, line, _____ or

WIPO Pub. No. _____, page _____, line _____.

Related Information about Access to Pending Applications (37 CFR 1.14):

Direct access to pending applications is not available to the public but copies may be available and may be purchased from the Office of Public Records upon payment of the appropriate fee (37 CFR 1.19(b)), as follows:

For published applications that are still pending, a member of the public may obtain a copy of:

- the file contents;
- the pending application as originally filed; or
- any document in the file of the pending application.

For unpublished applications that are still pending:

- (1) If the benefit of the pending application is claimed under 35 U.S.C. 119(e), 120, 121, or 365 in another application that has: (a) issued as a U.S. patent, or (b) published as a statutory invention registration, a U.S. patent application publication, or an international patent application publication in accordance with PCT Article 21(2), a member of the public may obtain a copy of:
 - the file contents;
 - the pending application as originally filed; or
 - any document in the file of the pending application.
- (2) If the application is incorporated by reference or otherwise identified in a U.S. patent, a statutory invention registration, a U.S. patent application publication, or an international patent application publication in accordance with PCT Article 21(2), a member of the public may obtain a copy of:
 - the pending application as originally filed.

Shoaib Ghayour

Signature

Shoaib Ghayour

Typed or printed name

Registration Number, if applicable

703-553 0006

Telephone Number

09-01-06

Date

FOR PTO USE ONLY

Approved by:

SEP 01 2006

Unit:

File Information Unit

This collection of information is required by 37 CFR 1.14. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. BRING TO: File Information Unit, Crystal Plaza Three, Room 1D01, 2021 South Clark Place, Arlington, VA.



US006015567A

United States Patent [19]**Hudziak et al.**[11] **Patent Number:** **6,015,567**[45] **Date of Patent:** **Jan. 18, 2000**[54] **HER2 EXTRACELLULAR DOMAIN**[75] **Inventors:** **Robert Michael Hudziak**, San Bruno;
H. Michael Shepard, San Francisco,
both of Calif.; **Axel Ullrich**,
Martinsried, Germany[73] **Assignee:** **Genentech, Inc.**, South San Francisco,
Calif.[21] **Appl. No.:** **08/422,108**[22] **Filed:** **Apr. 14, 1995****Related U.S. Application Data**[62] Division of application No. 08/355,460, Dec. 13, 1994,
abandoned, which is a continuation of application No.
08/048,346, Apr. 15, 1993, abandoned, which is a continu-
ation of application No. 07/354,319, May 19, 1989, aban-
doned.[51] **Int. Cl.⁷** **A61K 38/00**; C07K 14/705;
C07K 19/00[52] **U.S. Cl.** **424/277.1**; 424/185.1;
424/192.1; 424/278.1; 424/282.2; 530/402;
530/403[58] **Field of Search** 424/185.1, 192.1,
424/278.1, 277.1, 282.2; 530/402, 403[56] **References Cited****U.S. PATENT DOCUMENTS**

4,761,371	8/1988	Bell et al. .
4,877,611	10/1989	Cantrell .
4,935,341	6/1990	Bargmann et al. .
4,963,354	10/1990	Shepard .
4,968,603	11/1990	Slamon .
5,030,576	7/1991	Dull et al. .
5,081,228	1/1992	Dower et al. .
5,126,433	6/1992	Maddon et al. .
5,183,884	2/1993	Kraus et al. .
5,401,638	3/1995	Carney et al. .

FOREIGN PATENT DOCUMENTS

WO 89/01973	3/1989	WIPO .
WO 89/06692	7/1989	WIPO .
WO 89/10412	11/1989	WIPO .
WO 91/02062	2/1991	WIPO .

OTHER PUBLICATIONS

Yamamoto et al *Nature* 119: 230-234 1986.
 Derbin *PNAS* 83 9129-9133 1986.
 Mitchell et al *Cancer Res* 48: 5883-5893 1988.
 Hoover et al *Cancer* 55: 1236-1243 1985.
 Capon et al *Nature* 337: 525-531 1989.
 Tal et al *Cancer Res.* 48: 1517-1520 1988.
 Zhou et al *Cancer Res.* 47: 6123-6125 1987.
 Bernards et al *PNAS* 84: 6854-6858 1987.
 Ezell, C J. of *NIH Research* 7: 46-49 1995.
 Akiyama et al., "The product of the human c-erbB-2 Gene:
 a 185-Kilodalton Glycoprotein with tyrosine Kinase Activ-
 ity" *Science* 232:1644-1646 (1986).
 Bargmann et al., "The neu oncogene encodes an epidermal
 growth factor receptor-related protein" *Nature* 319:226-230
 (1986).

Bernards et al., "Effective tumor immunotherapy directed
 against an oncogene-encoded product using a vaccinia virus
 vector" *Proc. Natl. Acad. Sci. USA* 84:6854-6858 (1987).

Coussens et al., "Tyrosine Kinase Receptor with Extensive
 Homology to EGF Receptor Shares Chromosomal Location
 with neu Oncogene" *Science* 230:1132-1139 (1985).

Drebin et al., "Down-Modulation of an Oncogene Protein
 Product an Reversion of the Transformed Phenotype by
 Monoclonal Antibodies" *Cell* 41(3):695-706 (1985).

Drebin et al., "Inhibition of tumor growth by a monoclonal
 antibody reactive with an oncogene-encoded tumor anti-
 gen" *Proc. Natl. Acad. Sci.* 83:9129-9133 (1986).

Drebin et al., "Monoclonal antibodies reactive with distinct
 domains of the neu oncogene-encoded p185 molecule exert
 synergistic anti-tumor effects in vivo" *Oncogene* 2:273-277
 (1988).

Drebin et al., "Monoclonal antibodies specific for the neu
 oncogene product directly mediate anti-tumor effects in
 vivo" *Oncogene* 2(4):387-394 (1988).

Fendly et al., "The Extracellular Domain of HER2/neu Is a
 Potential Immunogen for Active Specific Immunotherapy of
 Breast Cancer" *Journal of Biological Response Modifiers*
 9:449-455 (1990).

Fendly et al., "Successful Immunization of Rhesus Monkeys
 with Extracellular Domain of p185^{HER2}: A Potential
 Approach to Human Breast Cancer" *Vaccine Research*
 2(3):129-139 (1993).

Graham et al., "A New Technique for the Assay of Infec-
 tivity of Human Adenovirus 5 DNA" *Virology* 52:456-467
 (1973).

Hopp et al., "Prediction of protein antigenic determinants
 from amino acid sequences" *Proc. Natl. Acad. Sci. USA*
 78(6):3824-3828 (1981).

Hudziak et al., "Amplified Expression of the HER2/ERBB2
 Oncogene Induces Resistance to Tumor Necrosis Factor α in
 NIH 3T3 Cells" *Proc. Natl. Acad. Sci. USA* 85:5102-5106
 (1988).

Hudziak et al., "Increased expression of the putative growth
 factor receptor p185^{HER2} causes transformation and tumori-
 genesis of NIH 3T3 cells" *Proc. Natl. Acad. Sci.*
 84:7159-7163 (1987).

Hudziak et al., "p185^{HER2} Monoclonal Antibody Has Anti-
 proliferative Effects In Vitro and Sensitizes Human Breast
 Tumor Cells to Tumor Necrosis Factor" *Molecular & Cel-
 lular Biology* 9(3):1165-1172 (1989).

Kane et al., "Formation of recombinant protein inclusion
 bodies in *Escherichia coli*" *Tibtech* 6:95-101 (1988).

(List continued on next page.)

Primary Examiner—Thomas M. Cunningham*Assistant Examiner*—Martha Lubet*Attorney, Agent, or Firm*—Wendy M. Lee[57] **ABSTRACT**

A method of treating a human patient via active immuno-
 therapy comprising administering an effective amount of
 extracellular portion of human HER2 receptor to the patient
 wherein the method provokes a cell-mediated immune
 response to HER2 receptor in the patient treated therewith.

26 Claims, 13 Drawing Sheets